

Guide for Reviewers for 1R44 SBIR Direct Phase II applications

Small Business Innovation Research (SBIR) Awards

Background:

NIH issued a SBIR 'Direct to Phase II' pilot solicitation [PAR-14-088](#) on February 5, 2014. The SBIR/STTR Programs were recently reauthorized by the United States Congress with the SBIR/STTR Reauthorization Act of 2011 (P.L. 112-81). One change that was made to the SBIR program in this reauthorization was the authority for certain participating federal agencies to 'issue a Phase II award to a small business concern that did not receive a Phase I award for that research/research & development' through FY 2017. This is a so-called 'Direct-to-Phase II' SBIR award. This authority would permit SBCs to submit Direct-to-Phase-II SBIR applications, if the small business had performed the Phase I stage-type of research through other funding sources. The legislative rationale for permitting the Direct-to-Phase II award is to allow a SBC that has already built a technology prototype and tested its feasibility (i.e. completed Phase-I-type R&D) to move directly into a Phase-II-type R&D that tests the functional viability of the prototype according to scientific methods and potential for commercial development. The Direct-to-Phase-II SBIR mechanism eliminates the need for the SBCs to propose additional small feasibility studies, if the technology is ready for the Phase II stage of development. The Direct-to-Phase II authority is **not** available to the STTR program.

Mechanics:

Only applications submitted to PAR-14-088 are considered SBIR Direct Phase II. This FOA accepts no other types of submissions (i.e. it does **not** accept Phase I, Fast-track or regular Phase II or IIB). Likewise, the SBIR Omnibus and other SBIR FOAs do **NOT** accept SBIR Direct Phase II submissions. SBIR Direct Phase II applications will have a grant code '1 R44 IC123456-01' which is identical to a Fast-track designation. The only way to tell a Direct Phase II (at this time) is that it is submitted to PAR-14-088.

A SBIR Direct Phase II is nearly identical to a regular Phase II with a few exceptions. Since there is no Phase I award prior, but applicants must have done the Phase I-equivalent work on their own, applicants must describe their Phase I-like work, similar to a Phase I progress report, in their application.

Direct Phase II applicants are given the following additional instructions:

PHS 398 Research Plan

All instructions in the SF424 (R&R) SBIR/STTR Application Guide must be followed, with the following additional instructions:

3. Research Strategy. Summarize the specific aims of the preliminary work that forms the basis for this Phase II application, quantitative milestones (a quantitative definition of success) for each aim, the importance of the findings, and emphasize the progress made toward their achievement. Describe the technology developed, its intended use and who will use it. Provide data or evidence of the capability, completeness of design, and efficacy along with the rationale for selection of the criteria used to validate the technology, prototype, or method. Describe the current status of the product (e.g., under development, commercialized, in use, discontinued). If applicable, describe the status of FDA approval for your product, process, or service (e.g., continuing pre-IND studies, filed on IND, in Phase I (or II or III) clinical trials, applied for approval, review ongoing, approved, not approved). List the generic and/or commercial names of products. A list of publications, patents, and other printed materials should be included in Item 5 (Progress Report Publication List); do not include that information here.

Review:

Direct to Phase II SBIR applications will be reviewed in CSR SBIR/STTR study sections. Direct to Phase II SBIR applications should be reviewed with regular Phase IIs. It is strongly recommended that reviewers refer to the Direct Phase II [PAR-14-088](#). Applicants must provide a separate Commercialization Plan as this is a Phase II.

The SBIR Direct to Phase II review criteria are nearly identical to the regular Phase II review criteria:

How well did the applicant demonstrate feasibility of the methodology or technology equivalent to meeting **Phase I-level** objectives, and providing a solid foundation for the proposed Phase II activity?

These applications should be treated by-and-large like regular Phase II applications.